

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 29 SEP 2005

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Applicant's or agent's file reference 213838-00067	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEPA/416)	
International application No. PCT/US03/17873	International filing date (day/month/year) 05 June 2003 (05.06.2003)	Priority date (day/month/year) 05 June 2002 (05.06.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 39/00; C12Q 1/68; C07H 21/04 and US Cl.: 424/185.1; 435/6; 536/24.31		
Applicant BAYLOR COLLEGE OF MEDICINE		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>    </u> sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input checked="" type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 05 January 2005 (05.01.2005)	Date of completion of this report 20 August 2005 (20.08.2005)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>Valerie J. Belt-Harris</i> G. R. Ewoldt, Ph.D. Telephone No. 571-272-1600	

Form PCT/PEPA/409 (cover sheet)(July 1998)

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/17273

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed.
- ☒ the description:  
pages 1-28 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages 29-32, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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PCT/US03/17873**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>4-21</u>	YES
	Claims <u>1-3</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-18</u>	NO
Industrial Applicability (IA)	Claims <u>1-21</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-3 lack novelty under PCT Article 33(2) as being anticipated by Hong et al. (1999) or Hong et al. (2000). The references teach an oligonucleotide encoding SEQ ID NO:6, see Table II in both documents.

Claims 4-18 lack an inventive step under PCT Article 33(3) as being obvious over Hong et al. (1999) or Hong et al. (2000). As set forth above, the references teach an oligonucleotide encoding SEQ ID NO:6. The references further associate the polypeptide of SEQ ID NO:6, T cell receptor (TCR) Vβ9, with multiple sclerosis (MS). Accordingly, the references render obvious the PCR primers, kit, and methods of using said primers for the detection of MS set forth in the claims.

Claims 1-21 meet the criteria set out in PCT Article 33(4), and thus establish industrial applicability because the subject matter claimed can be made or used in industry.

Claims 19-21 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a vaccine comprising one of the claimed sequences nor an effective method of treating an autoimmune disease employing said vaccine.

----- NEW CITATIONS -----

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/17873

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 19-21 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because the claimed vaccine and method of treating an autoimmune disease is not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because: the disclosure fails to establish that the claimed vaccine would provide an effective treatment for an autoimmune disease. Indeed, the only autoimmune disease that the polypeptides of the claims can even be associated with is MS. And additionally, a mere association with a disease does not provide enablement for the treatment of said disease.